REMARKS:

REMARKS REGARDING ELECTION:

It is respectfully pointed out that claims 23-45 which are subject to restriction had previously not been cancelled, but instead had been withdrawn. In view of the finality of the requirement, however, these claims have now been cancelled.

REMARKS REGARDING CLAIMS AMENDMENTS:

Claim 17 has been amended to remedy the rejection under 35 U.S.C. § 112, second paragraph and thus it is requested that Examiner reconsider and withdraw the rejection of the claim on that basis.

IN RESPONSE TO THE OFFICE ACTION:

REJECTIONS UNDER 35 U.S.C. § 103:

Claims 1-22 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Richmond (US 5445630).

Applicants request that Examiner reconsider and withdraw the above rejection of the claims in view of the following:

By way of background, it should be appreciated that devices configured according to the teachings of the present invention are mixing devices which comprise a first portion and a second portion, each of which are made of different materials and connected to each other by means of a combined friction coupling and snap connection.

An accordingly configured device enables mixing of medical fluids. The first portion has a spike with an inlet port 101 and can be connected to an infusion bag comprising a first medical substance. Injection of a second medical substance can be performed by use of an injection needle penetrating a fluid-proof membrane 106 of an injection port 102.

The second portion provides an outlet port 103 for exit of a mixed flow of the first and second medical fluids.

Because of the division of the device into the first and second portions, the second portion can advantageously be constructed from an elastomeric polymer material that is more resilient than the material of the first portion which may exemplarily and advantageously be constructed from a thermoplastic polymer material. The ability to utilize such diverse materials affords several important beneficial functions.

Among others, this special coupling enables the device to be assembled from a minimum of individual components without any use of glue or adhesive. The less resilient material of the first component ensures that the inlet and injection ports are sufficiently shape-permanent during use, whereas the more resilient material of the second portion is capable of providing the requisite sealing action between the first and second portions, and between the second portion and an additional component.

Another attribute of utilizing a more resilient material for the second portion is that an additional component can be connected to the device (see Fig. 4) in a similar way as the first portion is connected to the infusion bag. Thus, the second portion allows leak-proof insertion of a rigid spike (which could be the first portion of a further device according to the invention) into the outlet port in order to create an infusion line, for instance.

Furthermore, the device can be adapted for several applications by combining the first portion with differently designed second portions.

Now turning to US 5,445,630 issued to Richmond: as an initial point, Richmond '630 does not describe a mixing device as expressly recited by Applicant.

Moreover, the port 176 which Examiner has cited as an "injection port" is in fact not an injection port, but is instead only a ventilation channel. More particularly, the "spike" of Richmond '630 is vented as described therein at column 6, lines 38-52 (see excerpt immediately below).

(*Richmond '630, column 6, lines 38-52*) FIG. 6 shows a spike 174 which is a vented spike, i.e., the spike 174 has a gas tube 176 defining a gas passageway 178, and the gas passageway 178 is in fluid communication with a first fluid passageway 180 of the spike 174.

Preferably, a hydrophobic membrane 182 is positioned athwart the gas passageway 178, and a ball 184 is positioned for reciprocating movement within the gas passageway 178. The ball 184 can contact a seat 186 that is formed in the gas tube 176 to block fluid flow through the gas passageway 178. On the other hand, gas within the fluid passageway 180 will urge the ball 184 away from the seat 186 to permit the gas to pass out of the fluid passageway 180 through the gas passageway 178 and hydrophobic membrane 182. The spike 174 also has a female luer fitting with valve 188.

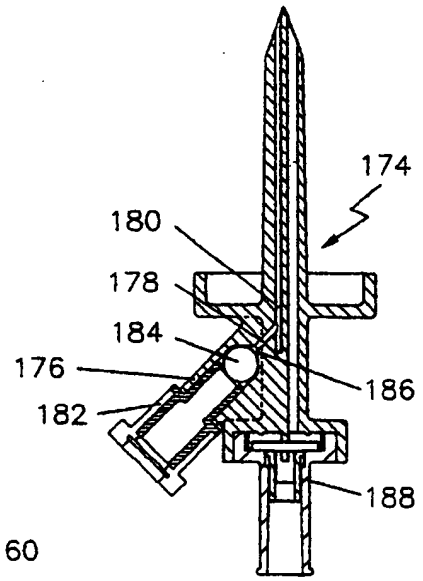


FIG.6.

The other port has a first luer fitting portion with a valve to permit fluid flow through the spike when a corresponding second luer fitting portion is engaged to the first luer fitting portion and to prevent fluid flow through the spike when the second luer fitting portion is not connected to the first.

It must be appreciated that luer fittings are well known in the art as being standard components in which a first luer fitting portion and a second luer fitting portion are conical fittings with or without a thread. Therefore, it is respectfully asserted that such a luer fitting as stated by the Examiner cannot constitute a second portion of the device and be regarded as a combined friction coupling and snap connection between a first and a second portion of a resulting device.

Still further, there is no citation supporting Examiner's position that it would be obvious to a person skilled in the art to separate the one-piece spike device of Richmond '630 into two portions, which portions are connectable to each other by means of a combined friction and snap connection as expressly recited by Applicant. Moreover, the one piece construction of Richmond '630 amounts to a "teaching away" from the two-portion construction recited by Applicant, and particularly the two-portion construction wherein the second portion is constructed from material that is more resilient than the material of the first portion, which are intended to be connectable to each other by a combined friction and snap connection.

Equally as important is the fact that the device of Richmond '630 would be rendered unworkable if divided into two portions as recited by Applicant, but connected to each other by a combined friction and snap connection; specifically, it would not be possible to make the luer fitting from a more resilient material in accordance Applicant's recited invention because the luer fitting has to be made of a relatively hard rigid material to ensure proper functioning.

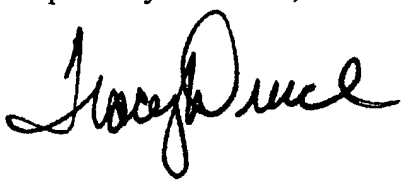
In view of the above, Applicant submits that the requirement and burden of presenting of a *prima facie* case of obviousness under 35 USC §103 has not been presented. Therefore Applicant requests reconsideration and withdrawal of the rejection of the claims under 35 USC §103.

It is believed that the above amendments and remarks place the application in condition for allowance. Therefore, a Notice of Allowance is respectfully solicited.

The undersigned representative authorizes the Commissioner to charge any additional fees under 37 C.F.R. 1.16 or 1.17 that may be required, or credit any overpayment, to Deposit Account No. 14-1437, referencing Order No. 06730.0020.NPUS00.

In order to facilitate the resolution of any issues or questions presented by this paper, the Examiner should directly contact the undersigned by phone to further the discussion.

Respectfully submitted,



Tracy W. Druce
Patent Attorney
Reg. No. 35,493
Tel. 202.293.7333